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10 IMPAX LABORATORIES, INC.

11 UNITED STATES DISTRICT COURT
12 NORTHERN DISTRICT OF CALIFORNIA

13 IMPAX LABORATORIES, INC.,

14 Plaintiff,

15 v.

16 ALZA CORPORATION,

17 Defendant.

HOWARD
RICE
NEMEROVSKI
CANADY
FALK
& RABKIN
A Professional Corporation

ORIGINAL
FILED

FILED OCT 24 2003

WDB

C No. 3 4795

COMPLAINT

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1 Plaintiff IMPAX Laboratories, Inc. ("IMPAX") by way of its Complaint alleges as
2 follows:
3

4 THE PARTIES

5 1. IMPAX is a corporation organized and existing under the laws of the State of
6 Delaware and has its principal place of business at 30831 Huntwood Avenue, Hayward,
7 California 94544.

8 2. On September 4, 2003, Alza Corporation ("Alza") filed a Complaint with this
9 Court in Case No. 03 04032 WDB ("the Alza Complaint"). In the Alza Complaint, Alza
10 alleged that it is a corporation organized and existing under the laws of the State of Delaware
11 and has its principal place of business at 1900 Charleston Road, Mountain View, California
12 94043.

13 JURISDICTION AND VENUE

14 3. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§2201 and
15 2202, and the Patent Laws of the United States, 35 U.S.C. §1 et seq.
16

17 4. This Court has subject matter jurisdiction based upon 28 U.S.C. §§1331, 1338(a),
18 2201 and 2202.

19 5. This Court has personal jurisdiction over Alza for at least the reason that Alza has
20 a place of business in California.

21 6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§1391 and
22 1400(b).
23

24 INTRADISTRICT ASSIGNMENT

25 7. Because this action is an Intellectual Property Action as specified in Civil L.R.
26 3-2(c), the action is to be assigned on a district-wide basis.
27
28

THE PATENTS AT ISSUE

8. In the Alza Complaint, Alza alleges that IMPAX infringes United States Patent No. 6,124,355 ("the '355 Patent"), which is entitled "Oxybutynin Therapy." In the Alza Complaint, Alza asserts ownership of the '355 Patent.

9. United States Patent No. 5,674,895 ("the '895 Patent") is entitled "Dosage Form Comprising Oxybutynin." On its face, the '895 Patent is assigned to Alza. A copy of the '895 Patent is attached as Exhibit A.

10. United States Patent No. 5,840,754 ("the '754 Patent") is entitled "Dosage Form Comprising Oxybutynin." On its face, the '754 Patent is assigned to Alza. A copy of the '754 Patent is attached as Exhibit B.

11. United States Patent No. 5,912,268 ("the '268 Patent") is entitled "Dosage Form and Method for Treating Incontinence." On its face, the '268 Patent is assigned to Alza. A copy of the '268 Patent is attached as Exhibit C.

12. United States Patent No. 6,262,115 B1 ("the '115 Patent") is entitled "Method for the Management of Incontinence." On its face, the '115 Patent is assigned to Alza. A copy of the '115 Patent is attached as Exhibit D.

THE ALZA NDA AND IMPAX ANDA

13. On information and belief, Alza is the holder of New Drug Application No. 20-897 for Ditropan XL® (oxybutynin extended released tablets), 5 mg, 10 mg, 15 mg (the "Ditropan Product").

14. The following five U.S. patents, among others, are identified in the U.S. Food and Drug Administration ("FDA") publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to the Ditropan Product: the '895 Patent, the '754 Patent, the '268 Patent, the '355 Patent, and the '115 Patent (collectively, "the Orange Book Patents"). Upon information and belief, Alza caused FDA to list the Orange Book Patents in the Orange Book.

15. IMPAX has submitted an Abbreviated New Drug Application ("ANDA") to

1 FDA, which was assigned No. 76-745 ("IMPAX ANDA"), for oxybutynin chloride extended
 2 release tablets, 5 mg, 10 mg, and 15 mg ("IMPAX Product"). The IMPAX ANDA and its
 3 subsequent amendment include certifications made pursuant to 21 U.S.C.
 4 §355(j)(2)(A)(vii)(IV) with respect to each of the Orange Book Patents (the "Paragraph IV
 5 Certifications").

6 16. On or about July 25, 2003, IMPAX, via Mr. Kendrew H. Colton, mailed to Alza a
 7 "Notice Under 21 U.S.C. §355(j)(2)(B)(i) and (ii), With Reference to U.S. Patent Nos.
 8 5,674,895; 5,840,674 [sic]; 5,912,268; 6,262,115; and 6,124,355" dated July 25, 2003 ("First
 9 Notice"), which states, inter alia, that FDA received from IMPAX the IMPAX ANDA that
 10 included, inter alia, the Paragraph IV Certifications. The First Notice further states, inter
 11 alia, that the '895 Patent, the '754 Patent, the '268 Patent, the '355 Patent, and the '115
 12 Patent "are invalid, unenforceable and/or not infringed, either literally or under the doctrine
 13 of equivalents, under any provision of Title 35 United States Code by the commercial
 14 manufacture, use, offer for sale, sale or importation of the proposed drug described in
 15 IMPAX's ANDA No. 76-745."

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16 17. On or about August 19, 2003, IMPAX, via Mr. Kendrew H. Colton, mailed to
 17 Alza a "Notice Under 21 U.S.C. §355(j)(2)(B)(i) and (ii), With Reference to U.S. Patent
 18 Nos. 5,674,895; 5,840,674 [sic]; 5,912,268; 6,262,115; and 6,124,355" dated August 19,
 19 2003 ("Second Notice"), which states, inter alia, that FDA received from IMPAX an
 20 amendment to the IMPAX ANDA that included, inter alia, the Paragraph IV Certifications.
 21 The Second Notice further states, inter alia, that the '895 Patent, the '754 Patent, the '268
 22 Patent, the '355 Patent, and the '115 Patent "are invalid, unenforceable and/or not infringed,
 23 either literally or under the doctrine of equivalents, under any provision of Title 35 United
 24 States Code by the commercial manufacture, use, offer for sale, sale or importation of the
 25 proposed drug described in IMPAX's ANDA No. 76-745."

27 THE PRESENCE OF A CASE OR CONTROVERSY

28 18. Under 35 U.S.C. §271(e)(2)(A), IMPAX's submissions of the Paragraph IV

1 Certifications to FDA constitute an "act of infringement" for subject matter jurisdiction
2 purposes for each of the Orange Book Patents.

3 19. In the Alza Complaint or elsewhere, Alza has never disavowed an intent to assert
4 that IMPAX infringes the '268 Patent, the '754 Patent, the '895 Patent, or the '115 Patent
5 (collectively, "the Unasserted Patents").

6 20. IMPAX has made, and will continue to make, substantial preparation in the
7 United States to manufacture, sell, and offer to sell the IMPAX Product.

8 21. Because Alza caused the FDA to list the Unasserted Patents in the Orange Book
9 but did not assert the Unasserted Patents in its Alza Complaint, even though the Unasserted
10 Patents cover the same technology and share substantial content, IMPAX has a reasonable
11 apprehension that Alza will bring suit for infringement of the Unasserted Patents at some
12 time in the future, either before or after the commencement of commercial marketing or sale
13 of the IMPAX Product.

14 22. To avoid legal uncertainty and to protect its substantial investment (and
15 anticipated future investment) in the IMPAX Product, IMPAX has brought these declaratory
16 judgment claims for the Unasserted Patents.

17
18 **COUNT I**
19 **(Declaratory Judgment of Noninfringement of the '895 Patent)**

20 23. IMPAX realleges paragraphs 1-22 above as if fully set forth herein.

21 24. A case or controversy exists between IMPAX and Alza concerning the alleged
22 infringement of the '895 Patent, which requires a declaration of rights by this Court.

23 25. The commercial manufacture, use, offer for sale, sale, or importation of the
24 IMPAX Product does not and will not infringe any claim of the '895 Patent.

25
26 **COUNT II**
27 **(Declaratory Judgment of Noninfringement of the '754 Patent)**

28 26. IMPAX realleges paragraphs 1-25 above as if fully set forth herein.

1 27. A case or controversy exists between IMPAX and plaintiff concerning the alleged
2 infringement of the '754 Patent, which requires a declaration of rights by this Court.

3 28. The commercial manufacture, use, offer for sale, sale, or importation of the
4 IMPAX Product does not and will not infringe any claim of the '754 Patent.

5
6 **COUNT III**
7 **(Declaratory Judgment of Invalidity of the '754 Patent)**

8 29. IMPAX realleges paragraphs 1-28 above as if fully set forth herein.

9 30. A case or controversy exists between IMPAX and plaintiff concerning validity of
10 the '754 Patent, which requires a declaration of rights by this Court.

11 31. All claims of the '754 Patent are invalid for failing to comply with the
12 requirements of the patent laws of the United States, 35 U.S.C. §§102, 103, or 112.

13
14 **COUNT IV**
15 **(Declaratory Judgment of Noninfringement of the '268 Patent)**

16 32. IMPAX realleges paragraphs 1-31 above as if fully set forth herein.

17 33. A case or controversy exists between IMPAX and Alza concerning the alleged
18 infringement of the '268 Patent, which requires a declaration of rights by this Court.

19 34. The commercial manufacture, use, offer for sale, sale, or importation of the
20 IMPAX Product does not and will not infringe any claim of the '268 Patent.

21
22 **COUNT V**
23 **(Declaratory Judgment of Noninfringement of Claims 4-5, 8-13, 18-21, and 26-31 of**
24 **U.S. Patent No. 6,262,115)**

25 35. IMPAX realleges paragraphs 1-34 above as if fully set forth herein.

26 36. A case or controversy exists between IMPAX and Alza concerning the alleged
27 infringement of the '115 Patent, which requires a declaration of rights by this Court.

28 37. The commercial manufacture, use, offer for sale, sale, or importation of the

1 IMPAX Product does not and will not infringe at least claims 4-5, 8-13, 18-21, and 26-31 of
2 the '115 Patent.

3
4 **COUNT VI**
5 **(Declaratory Judgment of Invalidity of Claims 1-3, 6-7, 14-17, and 22-25 of U.S. Patent**
6 **No. 6,262,115)**

7 38. IMPAX realleges paragraphs 1-37 above as if fully set forth herein.

8 39. A case or controversy exists between IMPAX and plaintiff concerning validity of
9 the '115 Patent, which requires a declaration of rights by this Court.

10 40. At least claims 1-3, 6-7, 14-17, and 22-25 of the '115 Patent are invalid for
11 failing to comply with the requirements of the patent laws of the United States, 35 U.S.C.
12 §§102, 103, or 112.

13 **PRAYER FOR RELIEF**

14 **WHEREFORE, IMPAX prays that this Court:**

15 A. Enter judgment that the commercial manufacture, use, sale, offer for sale, or
16 importation of the IMPAX Product does not and will not infringe any claim of the '895, '754
17 and '268 Patents;

18 B. Enter judgment that the commercial manufacture, use, sale, offer for sale or
19 importation of the IMPAX Product does not and will not infringe claims 4-5, 8-13, 18-21,
20 and 26-31 of the '115 Patent;

21 C. Enter judgment that all claims of the '754 Patent are invalid;

22 D. Enter judgment that claims 1-3, 6-7, 14-17, and 22-25 of the '115 Patent are
23 invalid;

24 E. Permanently enjoin Alza, its officers, agents, directors, servants, employees,
25 subsidiaries, and assigns, and all those acting under the authority of or in privity with it or
26 with any of them, from asserting or otherwise seeking to enforce, the '895 Patent, the '754
27 Patent, the '268 Patent, or the '115 Patent against IMPAX;

28 F. Award costs incurred by IMPAX in this action;

1 G. Declare this case exceptional and award reasonable attorneys' fees to IMPAX
2 pursuant to 35 U.S.C. §285; and

3 H. Grant such other and further relief as the Court deems just and proper.

4
5 DATED: October 21, 2003.

6 Respectfully,

7 NEIL A. SMITH
8 HOWARD, RICE, NEMEROVSKI, CANADY,
9 FALK & RABKIN
A Professional Corporation

10 By: 
11 NEIL A. SMITH

12 Attorneys for Plaintiff IMPAX LABORATORIES,
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CERTIFICATION OF INTERESTED ENTITIES OR PERSONS

Pursuant to Civil L.R. 3-16, the undersigned certifies that the following listed persons, associations of persons, firms, partnerships, corporations (including parent corporations) or other entities (i) have a financial interest in the subject matter in controversy or in a party to the proceeding, or (ii) have a non-financial interest in the subject matter or in a party that could be substantially affected by the outcome of this proceeding:

Chemical Company of Malaysia Berhad
J.P. Morgan Chase & Co
Orvet UK Ltd.
Teva Pharmaceutical Industries Ltd.
Teva Pharmaceuticals Curacao N.V.
Teva Pharmaceuticals Europe B.V. (Holding - Holland)
Teva Pharmaceuticals USA, Inc.

DATED: October 24, 2003.

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By: 

NEIL A. SMITH

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